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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,232	09/05/2000	Stewart M. Kume	SMP0179US02	7770

28075 7590 12/28/2004

CROMPTON, SEAGER & TUFTE, LLC  
1221 NICOLLET AVENUE  
SUITE 800  
MINNEAPOLIS, MN 55403-2420

EXAMINER

MENDEZ, MANUEL A

ART UNIT	PAPER NUMBER
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3763

21

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/655,232

Applicant(s)

KUME, STEWART M.

Examiner

Manuel Mendez

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6-9, 13-21 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-9, 13-21 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

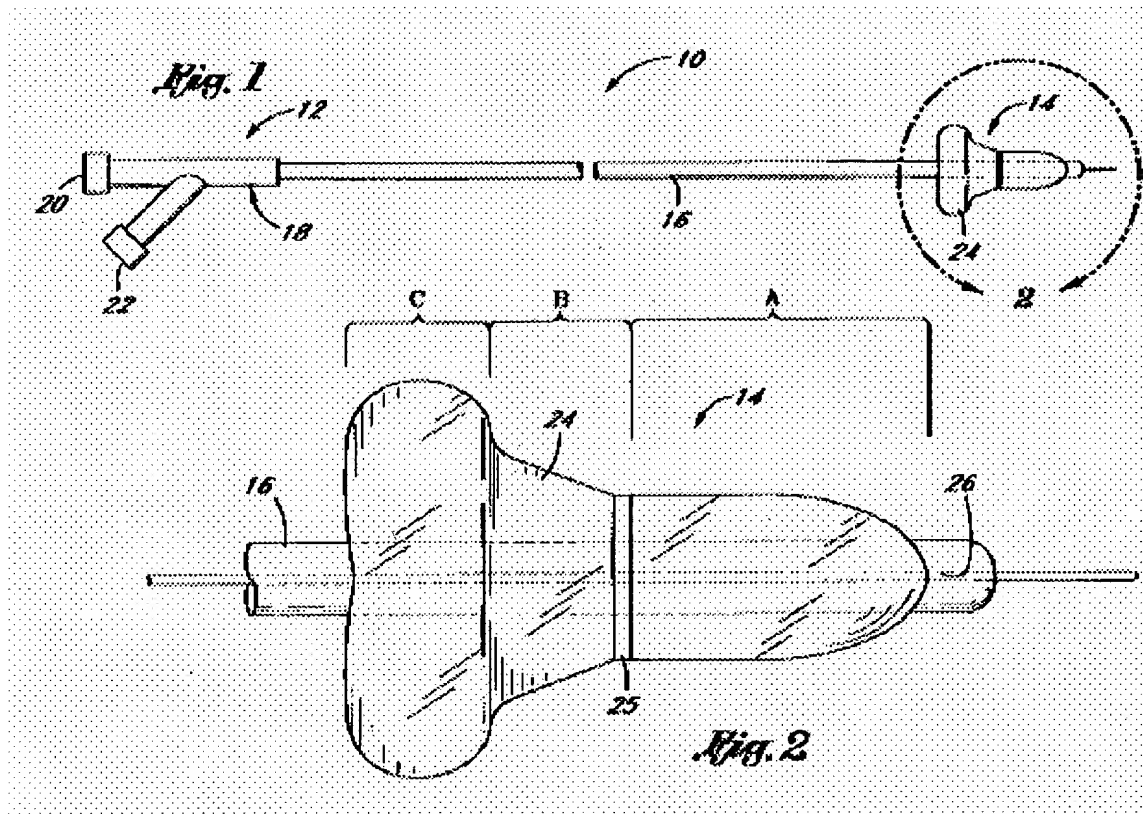
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 6, 18, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Myler.



The cited patent shows in figures 1 and 2, an elongate catheter body, an expandable member attached to the distal end of the catheter body, and a marker positioned on the expandable member. In relation to the limitation disclosing a plurality of markers; in column 3, lines 59-65, the specification states, the **"balloon 24 is preferably provided with one or more radiopaque marker bands such as a mid-balloon marker band 25"**. Accordingly, the subject matter presented in claims 6, 18, and 27 is anticipated by the teachings of the Myler Patent.

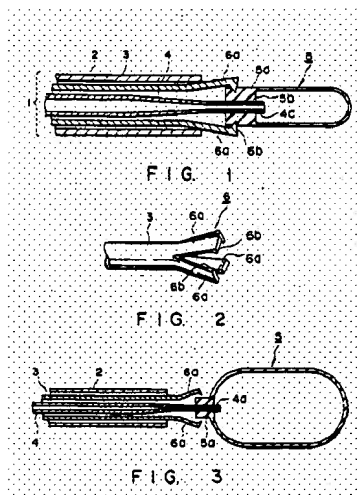
**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

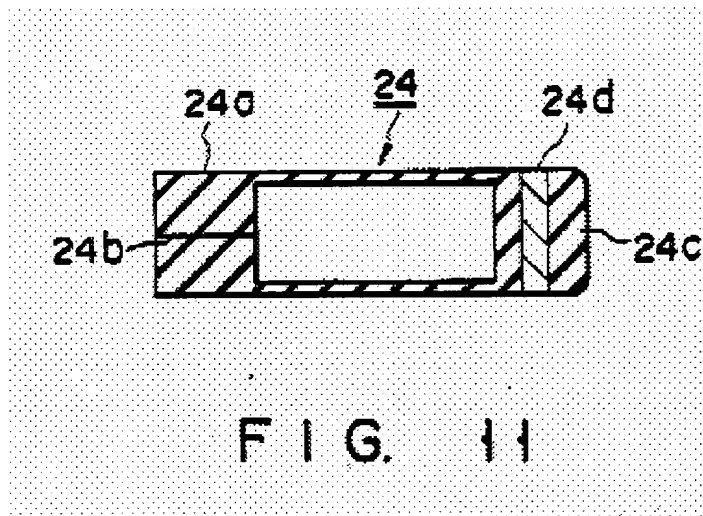
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 7-9, 12-17, 19-21, 24-26, and 28-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Myler in view of Ishida, et al., and Becker, et al.**

The Myler Patent discloses an elongate catheter body, an expandable member attached to the distal end of the catheter body, and a marker positioned on the expandable member. In relation to the plurality of markers, in column 3, lines 59-65, the specification states, the **"balloon 24 is preferably provided with one or more radiopaque marker bands such as a mid-balloon marker band 25"**. Since there is more than one marker, a pattern of markers is created on the surface of the balloon.

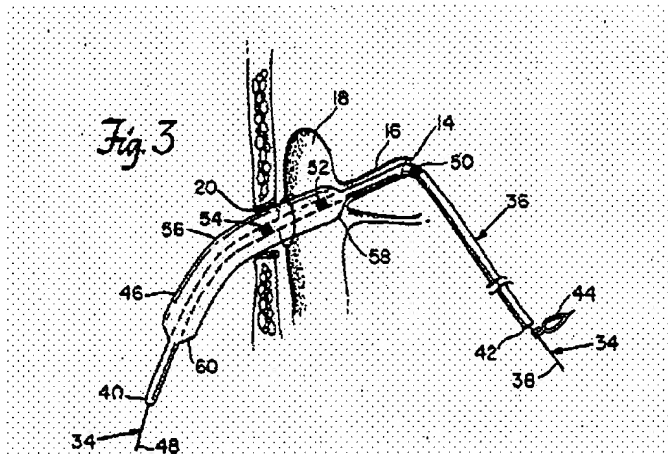


Similarly, in figures 1 and 3, the Ishida, et al., Patent shows an elongate catheter body, an expandable member attached to a distal end of the catheter body; and opaque markers positioned on the expandable member. In column 4, line 19, the specification states: "the material of the balloon (5) may be mixed with X-ray opaque substance such as platinum, gold or the like which constitutes a marker".



Moreover, in column 6, line 55, referring to figure 11, the specification states: "the distal portion (24c) of the balloon (24) may be made solid, and a belt-type marker (24d) made of x-ray opaque substance as described above may be fixed to or embedded in the outer peripheral surface portion (24c)". Based on the teachings of Ishida, et al., it would have been obvious to make the outer wall of a balloon with a mixture of radiopaque materials or by using belt-like marker as suggested in the figure above.

Finally, neither Ishida, et al., nor Myler teach the use of ink as a marker. However, the use of ink as a marker is conventional in the art as evidenced by the teachings of Becker, et al.



The Becker, et al., Patent demonstrates in figure 3 (above), that it is conventional in the art to use ink as a marker (50) in the outer wall of a catheter. Accordingly, based on the teachings of the cited patents, it would have been obvious for a person of ordinary skill in the art to enhance or modify the structure of Myler or Ishida, et al., with the use of ink as a marker in the outer surface of any portion of the catheter including the inflatable balloon.

### **Conclusion**

In view of the new grounds for rejection, this action is not final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Application/Control Number: 09/655,232  
Art Unit: 3763

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A handwritten signature in black ink, appearing to read 'Manuel Mendez', written in a cursive style.

Manuel Mendez  
Primary Examiner  
Art Unit 3763

December 27, 2004